510(K) Summary
for the APEX Spine System

JUL 26 2011

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for the APEX Spine System with the added Cannulated Pedicle Screws

Date Prepared: 6/14/2011

1. **Submitter:**
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Contact Person:
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Director of Regulatory Affairs.
SpineCraft, LLC
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2. **Trade name:** APEX Spine System Cannulated Screws
Common Name: Pedicle screw system
Classification Name: Pedicle screw spinal system per MNI 888.3070
Pedicle screw spinal system per MNH 888.3070
Pedicle screw spinal system per NKB 888.3070
Spinal interlaminal fixation orthosis per KWP 888.3050
Spinal intervertebral body fixation orthosis per KWQ 888.3060
Device Class: Class III
Classification Panel: Orthopedics

3. **Predicate or legally marketed devices which are substantially equivalent:**

- APEX Spine System (K062513 / K092825 / K102488) / SpineCraft
- Viper Spine System (K090648 / K102701) / DePuy Spine
- Polaris Spinal System (K103393 / K100409 / K100438) / BIOMET Spine / EBI, L.P.
- Synthes Pangea System (K052123) / Synthes Spine

4. **Description of the device:**

The purpose of this submission is to add cannulated screws to the APEX Spine System and add indications for use of the APEX Spine System in a posterior percutaneous approach and product code NKB. The APEX Spine System Cannulated Screws have exactly the same geometry of the APEX screws with the addition of a cannulation. The screws are available in a variety of diameters and lengths and can be used with the components of the previously cleared APEX Spine System.

Materials:

Titanium alloy per ASTM F136

Function:

The APEX Spine System is indicated for 1)non-cervical spinal fixation devices intended for posterior, non-pedicle fixation, 2)for non-cervical pedicle screw fixation and 3)hook fixation systems of the non-cervical spine, 4)for degenerative disc disease.

5. Substantial equivalence claimed to predicate devices

APEX Spine System with the added cannulated pedicle screws is substantially equivalent to the APEX Spine System (K062513 / K092825 / K102488), Viper Spine System (K090648 / K102701), Polaris Spinal System (K103393 / K100409 / K100438) and Synthes Pangea System (K052123) in terms of intended use, design, materials used, mechanical safety and performances,. The table below compares the features and characteristics of the APEX Spine System with the added Cannulated Pedicle Screws to these predicate devices.

Device Name / Items	APEX Spine System	APEX Spine System	Viper Spine System	Polaris Spinal System	Synthes Pangea System
Sponsor	SpineCraft	SpineCraft	DePuy	BIOMET Spine / EBI, L.P.	Synthes Spine
510(k) Number	Current submission	K062513 / K092825 / K102488	K090648 / K102701	K103393 / K100409 / K100438	K052123
For percutaneous use	Yes	No	Yes	Yes	Yes
Rod material	Titanium alloy per ASTM F136 & CoCr	Titanium alloy per ASTM F136 & CoCr	Titanium alloy & CoCr	Titanium alloy per ASTM F136	Pure Titanium per ASTM F67 and Titanium alloy per ASTM F-1295
Rod geometry	Straight & curved	Straight & curved	Straight & curved	Straight & curved	Straight
Screw loading	Top	Top	Top		
Screw material	Titanium alloy per ASTM F136 & CoCr	Titanium alloy per ASTM F136 & CoCr	Titanium alloy & CoCr	Titanium alloy per ASTM F136	Pure Titanium per ASTM F67 and Titanium alloy per ASTM F-1295
Monoaxial screw diameter	Yes	Yes	Yes	Yes	Yes
Polyaxial screw diameter	Yes	Yes	Yes	Yes	Yes
Cannulated screws	Yes	No	Yes	Yes	Yes
Crosslinks	Yes	Yes	Yes	Yes	
Hooks?	Laminar and Pedicle Hooks	Laminar and Pedicle Hooks	Yes	yes	
Sterility	Non-sterile, steam sterilized at hospital	Non-sterile, steam sterilized at hospital	Non-sterile, steam sterilized at hospital	Non-sterile, steam sterilized at hospital	Non-sterile, steam sterilized at hospital

6. **Intended Use:**

The APEX Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudoarthrosis).

The APEX Spine System is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, with the device fixed or attached to the lumbar and sacral spine (levels of pedicle screw fixation are L3 to S1), and for whom the device is intended to be removed after solid fusion is attained.

The APEX Spine System is also a hook and sacral/iliac screw fixation system of the non-cervical spine indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudo-arthrosis).

When used in a percutaneous, posterior approach with AIM Spine MIS instrumentation, the APEX Spine System is intended for non-cervical pedicle fixation for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed prvious fusion in skeletally mature patients . Levels of fixation are for the thoracic, lumbar and sacral spine.

7. **Non-clinical Test Summary:**

The following tests were conducted:
ASTM F1717-09, "Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model". Testing included Static Compression Bending Tests, Static Torsion Tests and Dynamic Compression Bending Tests. The results of this testing were compared to predicate systems, with the results being equal or higher than the predicate systems.

8. **Clinical Test Summary**

No clinical studies were performed

9. **Conclusions Nonclinical and Clinical**

The APEX Spine System is substantially equivalent to the predicate devices in terms of indications for use, design, material, performance and function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SpineCraft, LLC
% Ms. Ami Akallal-Asaad
Director of Regulatory Affairs
2215 Enterprise Drive
Westchester, Illinois 60154

JUL 26 2011

Re: K110906
Trade/Device Name: APEX Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI, KWQ, KWP
Dated: June 14, 2011
Received: June 17, 2011

Dear Ms. Akallal-Asaad:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A. Indication for Use Statement

510(k) Number (if known): K 110906

Device Name: APEX Spine System

Indication for Use:

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Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110906